REMARKS

This Amendment is in reply to the Final Office Action mailed May 25, 2005, for which an unextended response is due August 25, 2005. Claims 4-14, 16 and 18-25 are pending in the instant application. The allowance of claims 4-14 and 16 is noted with appreciation. Claims 18-20 and 25 are canceled, without prejudice. Applicants respectfully reserve the right to pursue the subject matter of the canceled claims herein in a future continuing application.

It was noted in the outstanding Final Office Action that claims 21-25, while objected to as being dependent upon a rejected base claim, would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. To this end, claims 21 and 23 are currently amended in order to advance prosecution on the merits. No new matter has been added.

Claim 21 has been rewritten in independent form and includes all of the limitations of the rejected base claim (*i.e.*, claim 18) and any intervening claims (*i.e.*, claims 19 and 20). Amended claim 21 is now drawn to a vaccine for inducing an immune response against HSV which comprises a plasmid expression vector comprising a gene encoding a carboxy-terminal truncated gB protein comprising the amino terminal 707 amino acids of wild type gB, said gene being operably linked to a transcription promoter, and a pharmaceutically acceptable carrier. No new matter has been added.

Claim 23 has been rewritten in independent form and includes all of the limitation of the rejected base claim (*i.e.*, claim 18) and any intervening claims (*i.e.*, claim 19). Amended claim 23 is now drawn to a vaccine for inducing an immune response against HSV which comprises a plasmid expression vector comprising a gene encoding HSV protein gD, said gene being operably linked to a transcription promoter, and a pharmaceutically acceptable carrier. No new matter has been added.

Applicants request that the above amendments to the claims be entered. Any omission of subject matter by amendment of the claims is done without prejudice to pursuing the same in a continuation or divisional application.

Rejection of Claims 18-20 under 35 U.S.C. §102(b)

Claims 18-20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Burke (Reviews of Infectious Diseases 13 (Suppl. 11):S906-911 (1991)). Claims 21-25 have additionally been objected to for being dependent upon said rejected claims. The Examiner takes the position that, while the rejected vaccine claims require a pharmaceutically acceptable

carrier, "since the expression vectors of Burke are added to cells in culture, the expression vectors are necessarily in an aqueous solution. . . . [which] meets the broad limitation of a pharmaceutically acceptable carrier." Applicants respectfully traverse.

Applicants assert that the aqueous solution used to solubilize the expression vector described in Burke for purposes of transfection into a Chinese hamster ovary cell line is not "necessarily" an aqueous solution which fits the definition of a pharmaceutically acceptable carrier. Inherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art reference. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). Thus, the "mere fact that a certain thing *may result from a given set of circumstances* is not sufficient." *Id.* (quoting *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). The pharmaceutically acceptable carrier recited in claims 18-20 accompanies a plasmid expression vector as part of a vaccine to be administered to a vertebrate (*e.g.*, human) for the generation of a protective immune response against HSV. Thus, the pharmaceutically acceptable carrier must be compatible with the *in vivo* transfer of plasmid DNA into said animal. While Burke does not specify a specific transfection protocol, of the many transfection methods used to introduce nucleic acids into eukaryotic cells in culture, one of the most popular relies on DNA coprecipitation with calcium phosphate or cationic polymers. This method consists of the formation of a fine precipitate of polyanionic nucleic acids with calcium phosphate or a high molecular weight cationic polymer (*e.g.*, DEAE-dextran) which is dispersed onto the cultured cells and then phagocytosed. However, the popularity of this transfection method stems more from its simplicity and low cost than from its efficiency, reproducibility and/or safety. In particular, it is well known both that said DNA precipitates are not effective in transfecting most primary cells or cells within an *in vivo* context and that the chemicals used are often toxic to cells. As such, the coprecipitation method is essentially restricted to *ex vivo* transfection of phagocytic cells. Thus, Applicants argue that the transfection method used in Burke does not necessarily result in the combination of the described plasmid DNA with an aqueous "pharmaceutically acceptable carrier" that alternatively can be used as part of a polynucleotide vaccine for administration to a vertebrate.

While Applicants maintain that Burke does not anticipate the vaccines of claims 18-20 for the reasons presented above, Applicants have canceled said claims without prejudice to pursuing, in a separate application, any subject matter canceled or omitted hereby. Applicants have further amended claims 21 and 23, and canceled claim 25, to remedy the claim objections resulting from the rejection of claims 18-20.

In view of the amendments and comments herein, Applicants respectfully take the position that claims 4-14, 16 and 21-24 are in proper form for allowance and a favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response, or if any of the claims are considered to require further amendment to be placed in condition for allowance after entry of this response.

Respectfully submitted,

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